Supporting Statement for Information Collection Request 1887.02

1 (a). Title

ICR: Personal Exposure of High-Risk Subpopulations to Fine Particles

EPA ICR Number: 1887.02

OMB Control Number: 2080-0058

1 (b) Short Characterization/Abstract

Approval was granted in 1999 for a series of four studies of personal exposure of high-risk subpopulations to particles and associated gases. Three of these studies have been completed, but the fourth is still continuing. The OMB-approved questionnaire expires July 31, 2002. This ICR requests a renewal for an additional three years. There is no new burden and no additional participants in the studies beyond what was calculated in the original ICR 1887.01.

The studies, which have been recommended by the National Academy of Sciences (NAS) under a directive from Congress, are considered necessary to support the proposed new National Ambient Air Quality Standard (NAAQS) for fine particles ($PM_{2.5}$). The information will be used by scientists within ORD and external to the Agency to determine the relationship between personal exposure, indoor concentrations, and concentrations measured at central monitoring site for one or more high-risk subpopulations, including particularly persons with chronic obstructive pulmonary disease (COPD) and persons with cardiovascular disease. The data will also be used by the Office of Air Quality Planning and Standards (OAQPS) in their review of the basis for the proposed $PM_{2.5}$ regulation. The information will appear in the form of final EPA reports, journal articles, and will also be made publicly available in an electronic data base.

2. Need for and Use of the Collection

2 (a) Need/Authority for the Collection

A number of epidemiological studies have linked daily mortality and morbidity statistics with increased particle concentrations measured outdoors. The mortality studies have taken place in many different cities around the world and appear to agree surprisingly well, showing an increase of a few percent in deaths per 50 ìg/m^3 increase in outdoor air particles, with no apparent threshold concentration. From a study of death certificates on days with higher pollution, the

affected persons appear to be those with existing respiratory disease (particularly those with chronic obstructive pulmonary disease, or COPD) and cardiovascular disease. Although the studies have often included other outdoor pollutants, such as sulfur dioxide, sulfates, and nitrogen oxides, the strongest relationships have generally been found to be with particles. Modeling studies have often suggested that it is the fine particles (less than 2.5 or 3.5 micrometers in diameter) that are the more likely agent. These findings have led the US EPA to propose a new National Ambient Air Quality Standard (NAAQS) for particles less than 2.5 micrometers in diameter ($PM_{2.5}$) of 65 ìg/m^3 for 24 hours (to be exceeded no more than once per year) and an annual standard of 15 ìg/m^3.

However, a number of studies of personal exposure to particles have shown little or no correlation of the personal exposure with concurrent outdoor air concentrations. This has led to concern for the adequacy of the scientific underpinning of the EPA standard. This concern was recognized by Congress in FY 1998 and resulted in their providing an increased budget to EPA to study the health effects of particles. Congress specified that the EPA should be guided in its research by the recommendations of a special National Academy of Sciences study of research needs. The resulting NAS report laid out a "portfolio" of recommended research over the next 13 years. In particular, the NAS report found that the relationship of the exposure of the high-risk subpopulations to outdoor concentrations was unknown, and recommended about three studies in different areas around the country to improve our knowledge of this relationship. The NAS estimated the cost of each of these studies as about $1M/year for three years, or a total of $9M over the three years.

Concurrently, EPA's Office of Research and Development (ORD), through its National Exposure Research Laboratory (NERL) had been planning a study along exactly the lines recommended by the NAS. A Request for Applications (RFA) was published in the Commerce Business Daily (CBD) on April 15, 1998, inviting proposals to study the exposure to fine particles of high-risk subpopulations. An external peer review panel reviewed the proposals and found that three were of high scientific value worthy of funding. EPA has funded all three proposals as competitive cooperative agreements. The three principal institutions include the Harvard School of Public Health, the New York University School of Medicine, and the University of Washington. In addition, EPA funded a fourth study using in-house personnel with contractual support. All four studies used the same basic questionnaire, approved by OMB in July of 1999 and due to expire July 31, 2002.

The goal of these studies is to determine the parameters of the relationship between personal exposure to particles, as measured by a personal monitor, and outdoor concentrations as measured at a central site, for a group of persons considered to be at high risk due to their respiratory or cardiovascular conditions. Of particular interest is the portion of the subjects' exposure that is due to outdoor sources. Since most persons are indoors most of the time, this requires measuring the rate at which outdoor particles are entering the home and also studying

the parameters, such as the penetration factor through the building envelope and the deposition rate of particles on interior surfaces, that affect the ultimate fate of the outdoor particles. Also, since it has been found that personal exposures differ from indoor concentrations, it is necessary to measure indoor concentrations at some location in the home as well as the personal and outdoor concentrations. Additionally, since it is still not certain that particles alone are responsible for the increased mortality on high-pollution days, gases that are associated with particles, such as carbon monoxide (CO), nitrogen dioxide (NO_2), and sulfur dioxide (SO_2) are being measured concurrently with the particles. Since the particle sizes associated with higher morbidity and mortality are also unclear, both fine and coarse particles will be measured. Fine particles are those less than 2.5 micrometers in aerodynamic diameter (A.D.); coarse particles are those between 2.5 and 10 micrometers in A.D.

One previous study of personal, indoor, and outdoor concentrations of particles has been carried out by EPA: the Particle TEAM (PTEAM) Study, carried out in 1990 in Riverside, CA. The questionnaire for that study was approved by OMB and has been used as the basis for developing the questionnaire for this study. Based on extensive analysis of the PTEAM questionnaire, some questions have been found not to be as useful as could be wished and have been omitted from the present questionnaire, thus reducing the burden on the respondent.

2 (b) Practical Utility/Users of the Data

The data will show how well a central site can represent the actual exposure of selected members of the population most at risk. Since the proposed EPA regulation of $PM_{2.5}$ includes requirements for a large number of monitoring sites throughout the country, a knowledge of how well those sites can do their job is clearly of great practical utility. The main users of the data include scientists studying personal exposure to airborne pollutants, Federal and State regulators responsible for administering their respective laws regarding air pollution, and the regulated community.

Within EPA, users of the data include measurement scientists and modelers within ORD, and program analysts and regulators within OAQPS. Also within ORD, the office responsible for preparing the Particle Criteria Document, the National Center for Exposure Assessment (NCEA), will abstract the data for use in the Criteria Document.

State agencies responsible for running the State programs on monitoring air pollution will also scrutinize the data for information relevant to siting their stations.

In the private sector, members of the regulated community such as the American Petroleum Institute (API) and the Electric Power Research Institute (EPRI) will use the data to study the impact of their member companies on outdoor air pollution and the associated impact on personal exposure.

3(a) Non-duplication

Two earlier pilot studies of the exposure of COPD patients have been carried out, by the Harvard School of Public Health under the sponsorship of the API and the EPRI. The first study, in Nashville, included just 10 patients who were followed for only 6 days, 3 days with $PM_{2.5}$ measurements and 3 days with PM_{10} measurements. The number of subjects was too small and the number of days too short for reaching any conclusions, but the study served the purpose of demonstrating the feasibility of the approach. The second study, in Boston, included a larger number of subjects (18) and a greater number of days (6-18). However, the NAS has emphasized that studies should be done in many different areas of the country, due to the different sources, aerosol types, and meteorology encountered in different areas. Therefore the present set of studies has been designed to have fairly wide geographic coverage, with studies having been completed in Boston, New York, Atlanta, Fresno, Raleigh and Seattle. Two studies that remain in progress are taking place in Anaheim and Seattle.

Since other organizations are planning similar studies, EPA has set up a coordinating committee including the other sponsoring agencies and also the principal investigators of the associated universities to be sure that no duplication occurs. Private organizations such as API and EPRI are also represented on the committee. This committee held its first meeting in Boston in August, 1998, and the members are continuing to correspond and coordinate their studies closely. For example, the Health Effects Institute and the EPA collaborated on pilot studies in Boston and upper New York State to test the sampling methodology thoroughly before employing the instruments in the field. Also, the California Air Resources Board has contributed to carry out additional studies in Los Angeles, and EPRI added resources for additional pollutants to be measured in the Atlanta study.

3(b) Public Notice

EPA solicited public comment on this request for a renewal of its information collection plans by publishing a notice in the Federal Register on April 2, 2002 (67 FR 15565). No comments were received.

3(c) Consultations

We have consulted on an informal basis with our respondents regarding the burden of the study, both from wearing the personal monitors and providing space in the home for the indoor monitors, and from answering the questionnaire. Comments were received indicating that the burden of wearing the monitors was sometimes noticeable; that it was sometimes difficult to keep children from exploring the area of the home reserved for indoor monitoring; and that answering the questionnaire was sometimes slightly boring. However, no respondents (out of more than 200 so far) have broken off their data collection before the planned end of their

participation, so we infer that the burden of the study is being well accepted by all respondents, who are of course all volunteers with no compulsion to participate.

3(d) Effects of Less Frequent Collection

Since this is a one-time study, this section is not applicable.

3(e) General Guidelines

We are adhering to OMB's general guidelines as described on page A-12 of EPA's ICR Handbook.

3(f) Confidentiality

The identity of the participants will remain confidential. All questionnaires and other data for each person have been identified with a unique number. All hard copy documents have this number as their identification, as do all entries in the electronic database. A single hard copy document relating the name of the person to the number is kept under lock and key by a single qualified individual at each of the institutions carrying out the study.

3(g) Sensitive Questions

There are no questions of a sensitive nature included on the questionnaire.

4 Respondents and Information Requested

4(a) Respondents/SIC Codes

Respondents have been and will be patients selected from certain diagnostic categories by cooperating physicians.

4(b) Information Requested

(i) Data Items

The data items requested are contained in the attached copy of the questionnaire and the associated instructions.

(ii) Respondent Activities

Of the six activities listed in the 1995 PRA Definition of "Burden," (3502. (2)) and the

nine activities listed in OMB's Definition of Burden in OMB's Final Rules (5 CFR 1320.3(b)(1) only the following three are relevant:

1. Reviewing instructions.

2. Completing and reviewing the collection of information.

3. Transmitting, or otherwise disclosing the information.

Our estimates of the amount of time it will take each respondent for each of these three activities are contained in our tables estimating burden.

5 The Information Collected--Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

The major agency activities associated with these studies are:

1. Monitoring progress of universities and contractors on main studies.
   8a. Reviewing progress reports.
   8b. Reviewing costs and schedule compliance.
   8c. Providing funds to the researchers on an annual basis.

2. Assisting in field sampling and analysis (including training of Agency personnel).

3. Analyzing data.

4. Writing, editing, and publishing final reports.

5. Creating and maintaining a publicly available electronic data base.

5(b) Collection Methodology and Management

Pretesting of the collection instrument was performed on several members of the university research teams. The time required to answer the questions was recorded and forms the basis of the estimates in the following tables.

Data are keyed into IBM-compatible PCs. Data quality have been and will be checked by 100% re-keying of the questionnaire items.

5(c) Small Entity Flexibility

This item is not applicable to this ICR.

5(d) Collection Schedule

The collection schedule varies somewhat between the three university consortia and the EPA/contractor study, but in all cases the household questionnaire is administered on the first day that the technicians arrive at the house. The daily 24-hour recall questionnaire is then administered on each day that the technicians collect the used personal monitor and provide a new monitor to the participant. In most cases, the respondent has been or will be monitored for between 6 and 14 successive days. In some cases, the respondent will be monitored again in a second season. The exact number of days that each respondent will be monitored depends on the schedule of the monitoring team and the respondent, and cannot be provided in this document.

6 Estimating the Burden and Cost of the Collection

6 (a) Estimating Respondent Burden

Table 1 provides our estimate of the respondent burden according to the three relevant categories appearing in OMB's final rules: reviewing instructions, completing the information collection, and transmitting/disclosing the information.

For reviewing the instructions, we assumed approximately 6 minutes per person. Based on our pretest, we found that the time to complete the questionnaire was approximately 12 minutes; we have assumed 24 minutes to allow for somewhat slower responses from our elderly population. We allowed an additional 6 minutes for transmitting/disclosing the information to the technician, although if there were no problems with filling out the questionnaire this activity (handing over the questionnaire) would take essentially no time. Thus we estimate the total time burden per day to be 36 minutes (0.6 h) per respondent. It should be noted that this table summarizes the total burden for all respondents, not just those remaining to be monitored.

6(b) Estimating Respondent Costs

Since participation is voluntary and an incentive payment is offered, there are no respondent costs or capital costs associated with the study.

6(c) Estimating Agency Burden and Cost

For the five Agency activities identified in Section 5, we have estimated an Agency burden and cost as shown in Table 2. Most items are self-explanatory. However, we note that

we have placed the extramural funding of $6M into Item 1c, Provision of Funds to Research Entities. Since each of the four consortia/contractors has a different breakout of labor categories and salaries, and since each of the consortia but one includes several subcontractors, it has not been feasible to provide a full breakout by category, labor hours, and costs. However, each lead University investigator has broken out his own labor costs by category and this information is included in Table 3. Again, it should be noted that these tables provide the total cost for all four studies; most of this cost has already been borne.

6(d) Estimating the Respondent Universe and Total Burden and Costs

The estimated burden per respondent was multiplied by the number of respondents to arrive at an estimate of the 3-year total and average annual respondent burden (Table 1).

6(e) Bottom Line Burden and Cost Tables

Tables 1 and 2 contain the total estimated respondent burden and Agency burden and costs.

6(f) Reasons for Change in Burden

There is no change in the total burden originally estimated in ICR 1887.01.

6(g) Burden Statement

The average total respondent burden is estimated to be 20.1 hours per person per year. This estimate includes the time for reviewing instructions, collecting and recording information, and transmitting the information to those administering the questionnaire.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, OP Regulatory Information Division, U.S. Environmental Protection Agency (2822T), 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Include the EPA ICR No. 1887.02 and OMB Control Number 2080-0058 in any correspondence.